

December 14, 1998

MEMORANDUM

SUBJECT: **OXYDEMETON METHYL**: HED Phase 2 Comments on the Gowan Company 30-day (error only) Response to the HED RED Preliminary Risk Assessment dated October 7, 1998.
Chemical No. 058702
Case No. 0258
Barcode: D251624

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In a letter dated November 27, 1998, Gowan Company provided their 30-day response to the HED Preliminary Risk Assessment for the Reregistration Eligibility Decision (RED) Document for Oxydemeton-methyl dated October 7, 1998. Following are the items Gowan noted as errors and HED's comment on those points.

Page 2 - Executive Summary: Regarding our Settlement Agreement not to market ODM on certain crops, it should be noted that an exception in this Agreement permitted regional sales in citrus, should pest conditions warrant the use. A 24(c) registration for use of ODM in citrus was subsequently approved.

HED's comment: HED is aware of the 24(c) registration for citrus and will note this exception in the revised preliminary risk assessment.

Page 7 - Dietary Exposure (food source): EPA has noted that "registrations are inactive" for blackberries, raspberries, potatoes and peas. We assume that the Agency means that no registrations exist for these crops.

HED's comment: The registrant's assumption is correct and this point will be clarified in the revised preliminary risk assessment.

Page 8 - Dietary Exposure (food source): Regarding the Agency's use of a minimum default assumption of 1% crop treated, we point out that this is, *a priori*, an error, since actual usage data are available.

HED's Comment: A minimum default assumption of 1% crop treated is routinely used by the Agency in all Tier 2 and Tier 3 dietary risk assessments; thus this is not an error in HED's dietary exposure assessment for oxydemeton-methyl. HED recognizes that actual oxydemeton-methyl usage data are available and that uses on some crops may be less than 1% of the crop treated, and in some cases (such as crops deleted from Gowan's marketing labels in 1994) there is no usage reported thus resulting in a value of 0% crop treated.

Page 9 - Dietary Risk Characterization: The Agency cites the use of a 10x safety factor for "inter-species variability" on a NOEL derived from a subchronic study with human volunteers. We assume that EPA means "intra-species" variability.

HED's Comment: The registrant is correct and the appropriate modification will be made in the revised preliminary risk assessment.

Page 17 - Postapplication Exposure: The Agency incorrectly states that climatological data are not available for the cauliflower portion of study MRID 43821401. An addendum to this study (MRID 44214001) supplied these data and was found acceptable. In addition, the Agency has overlooked information we provided on January 27, 1997 in conjunction with submission of the addendum MRID 44214001. Dislodgeable residues reported in the main study MRID 43821401 were based on single-sided leaf surfaces. Since the most recent guidance on foliar dislodgeable residues bases calculations on two-sided leaf surfaces, the reported residue values for all matrices are 2x the value that would be calculated using current guidelines. Associated MOEs are thus at least 2x the values calculated by the Agency.

HED's Comment: The registrant is correct on both points. The appropriate modifications regarding climatological data and calculations for foliar dislodgeable residues based on two-sided leaf surfaces will be made in the revised preliminary risk assessment.

Page 19 - Residue Chemistry Data: The Agency has reiterated its request for method validation data for corn forage, field corn grain and walnuts "at the revised tolerance levels" in conjunction with proposals for revised tolerances. As we noted in our letter to the Agency dated September 3, 1998, the proposal to lower tolerances in these matrices was apparently suggested by Bayer, the previous ODM registrant. We can find no record that a formal petition was ever prepared by Bayer. Gowan has not proposed, and has no plans to propose lower tolerances for the referenced matrices. For this reason, the additional validation data are not applicable.

HED's comment: Based on HED's review of available residue field trial data, the existing tolerances for residues of oxydemeton methyl and its sulfone metabolite in walnuts (0.3 ppm), corn grain (0.5 ppm), and corn forage/fodder (3 ppm), have been reassessed at lower levels of 0.05 ppm, 0.05 ppm, and 1 ppm, respectively. HED has required additional method validation data for these commodities showing recovery of residues of concern from samples fortified at the reassessed tolerance levels. These lower, reassessed tolerances were used in HED's DRES analysis for chronic dietary risk. This analysis estimated that risk to the highest exposed subgroup, non-nursing infants (<1 yr old) was 65% of the RfD. A revised analysis using the higher existing tolerances will occupy a greater % of the RfD. Should this revised Tier 2 analysis indicate a potential risk concern, additional refinements would be possible. HED recommends that a revision to the chronic dietary risk be conducted in conjunction with potential revisions to acute dietary risk when a final risk assessment is developed during Phase 4.